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a housing for housing at least one disposable injectate cartridge for an injectate to be injected from the system into a body;

disposable injectate-cartridges including:

an outer wall having an inner wall surface defining an inner chamber;

and

23  
a plunger engaging said inner wall surface and being movable in said chamber; said plunger defining an injectate-holding portion of said chamber, said injectate-holding portion of at least one cartridge comprising a rupturable seal dividing said holding portion into two compartments, one of said compartments holding a lyophilized part of an injectate and the other of said compartments holding a predetermined amount of fluid for mixing the components of the injectate; and said chamber having an injectate dispensing end having an exit nozzle, said plunger being drivable into said injectate-holding portion to dispense the injectate through said respective nozzles from said respective cartridges during the injection process;

latching and release apparatus for releasably latching of said cartridges held by said member to said housing during the injection process, and for releasing said cartridge held by said member from said housing, alternatively either without any physical contact by the user, for non-contaminating disposal after the injection process, or with physical contact by the user; and

a device for rupturing the seal of said cartridges.

#### REMARKS

One aspect of the present preliminary amendment is to correct certain errors in the drawings, which corrections are fully supported in the specification. Turning first to Figure 6, page 10 at the first paragraph, lines 1-5, describes a rupturable seal which is shown in dotted lines. Seal 56 forms

two compartments in the cartridge, one for lyophilized vaccine and the other for the fluid (diluent) to mix with it. The original Figure 6 omitted seal 56; it is shown in red on the attached drawing.

Support for the drawing changes in Figure 7 exists elsewhere in the application. The relative thickness of front plate 7 can be observed in Figures 2-5. Groove 19 is also shown in Figures 2-5. Cartridges 13 are shown in part in Figures 1, 2, 4 and 5, and in detail in Figure 6. A description of cartridges 13 can be found on page 9, lines 18-30. The location of piston 43 can be seen in detail in Figure 6. The location and operation of pistons 75 is explained on page 10, lines 27-31; page 11, lines 22-26; and page 12, lines 6-15. There are descriptions of cartridge sensor switches 79 on page 10, lines 29 – page 11, line 1; and page 11, lines 22-26. The foregoing items are shown schematically, and their location and schematic structure would be clear to those skilled in the art from the foregoing designated parts of the specification and of the drawings.

All of the changes to the drawings are shown in red in the attachments. It is requested that the Examiner approve these changes so that formal drawings can be prepared.

There were minor clerical errors on pages 8, 10 and 11, and they have been corrected by the present amendment. The marked-up portions of the specification are attached.

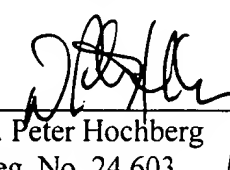
Entry of the attached new claims 53-63 is respectfully requested. The substance of new claims 53 and 59-63 is to define an aspect of the injection to either enable the use of the invention to release the containers or cartridges without contacting them (as, for example, when a nurse, doctor or medical assistant is injecting other persons) or by contacting them (as where the user is self-injecting and cross-contamination is not of concern). Contacting the container or the cartridge is inherent in the invention since clearly the user could manually load the release device. New claims 54-58 are directed to the aspect of the present invention discussed on pages 14-15 of the application and as shown in Figures 9-11.

Examination of the application in its merits is respectfully requested.

Respectfully submitted,

DPH/ck

By: \_\_\_\_\_

  
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Enc.: Proposed amendments to Figs. 2, 6 and 7

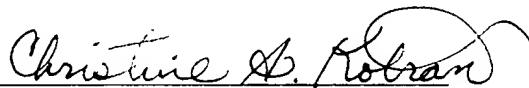
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Date: \_\_\_\_\_

March 28, 2002

  
Christine A. Kotran

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Nicholas F. D'Antonio, John T. Wagner and Richard O. Colvin  
Serial No. : 09/937,357  
Filed : September 24, 2001  
Title : HYPODERMIC INJECTION SYSTEM  
Attorney Docket : DX7119US (#90036)

**SECOND PRELIMINARY AMENDMENT  
MARKED-UP SPECIFICATION**

Paragraph straddling pages 7 and 8:

Front plate 7 is shown in further detail in Figure 3. As explained earlier, front plate 7 is one of many possible devices for holding the injectate containers, such as cartridges 13. Front plate 7 includes an external front surface 23 and a rearwardly extending portion 25 into the opposite sides of which are provided grooves 19. Front plate 7 can be slid into place and grabbed by locking members 17 near the front of housing 3, which are received in grooves 19, these members 17 being withdrawn upon the actuation of trigger 11. Alternatively, locking slides or the like can be removably inserted into grooves 19 to lock front plate 7 to housing 3 (of which the front end forms a part), the front plate being ejectable from the remainder of housing 3 once the locking members 17 are removed from grooves 19. Front end 7 further has holes 29 with holding surfaces 31 for gripping the forward ends of cartridges 13 which are preferably press fit into holes 29 to hold the cartridges in place. The outer surfaces of cartridge 13 can have a high friction surface if necessary, to assure a firm grip. Guard rings 33 are provided around each of holes 29 in order to prevent the splashing of blood or of injectate as it flows through the exit nozzle of cartridge 13, particularly during the injection process. An additional splash ring [35] 34 can also be provided, as shown in Figure 2, to add more protection against splashing.

Paragraph straddling pages 10 and 11.

Turning next to Figure 7, which is a cut-away view of system 1 without the handle or triggers discussed earlier[. System], system 1 has housing 3 and end plate 7, as explained earlier.

To avoid undue complexity in Figure 7, the means for ejecting or catapulting front plate 7 away from the injector are not shown. Housing 3 houses a carriage 57 which has extending from it rams or plunger rods [59] 60. A set of three springs 61 (for each of the three cartridges shown, there being six cartridges and springs in system 1) [extend] extends around the set of drive rods 63, each of which having nuts or movable spring supports 65. Supports 65 are movable along threaded rods 63 to provide a means to adjust spring preload and, therefore, injection pressure. Housing 3 has a rear wall 67, and springs 61 have their rear ends in contact with stationary wall 67. A set of holes 69 [are] is provided in wall 67 through which rods 63 pass and are movable. A cap or shoulder 71 is provided at the rear end of rod 63 for both preventing rod 63 from entering the inside chamber of housing 3 and for cooperating with a latching assembly discussed below. The latching assembly includes a solenoid 73 for each spring (however, only two are shown) and each having pistons 75 which in their energized state are inserted in front of caps 71 as part of the latching assembly. A cartridge sensor switch 79 is closed when a cartridge is installed in the appropriate holding portion of housing 3, thereby retracting piston 75 away from the path of moving rod 63 and cap 71. This is illustrated in the upper [position] portion of Figure 7.

Paragraph at the bottom of page 11.

In order to commence an injection with carriage assembly 57 in its set or cocked position and springs 61 in their cocked position as well, the user of system 1 actuates trigger 9. This action will either release a mechanical latch (not shown) or will provide a slight rotation to cam 81 to allow roller 89 to release as it moves onto the sharp drop off [87] 90 of cam 81.

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